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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,209	04/04/2000	Gary L. Breton	2709.1001001	9843

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EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/540,209

Applicant(s)

BRETON, GARY L.

Examiner

Sally A Sakelaris

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/12/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 and 29 is/are allowed.
- 6) ☒ Claim(s) 9, 10, and 30-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to Applicant's amendment and response received 5/12/2004 in response to the Non-final action mailed 2/12/2004. Claims 1-10 and 29-31 are now pending, claim 10 has been amended, while claims 29-31 are newly added. Claims 1-10 and 29-31 are currently under examination. Claims 1-8 have previously been deemed to be allowable over the prior art. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. All rejections not reiterated herein are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Korn et al. (Accession #Z98448, September 22, 1997).

Korn et al teach the nucleotide sequence consisting of at least twenty contiguous nucleotides of SEQ ID NO: 4084. (See attached alignment, Result 6). Korn et al. teach bases 180-199 (20 nucleotides) of Accession number Z98448 that align with 100% identity to bases 1164-1183 of SEQ ID NO: 4084.

Response to Arguments:

Applicant's arguments filed 5/12/2004 have been fully considered but they are not persuasive. Applicant argues that "although the cited sequence appears to comprise a sequence of 20 contiguous nucleotides also found in SEQ ID NO: 4084, the cited sequence does not 'consist of at least 20 contiguous nucleotides of ...SEQ ID NO: 4084'". Furthermore, applicant argues that "only elements that are not inconsistent with being a probe as described in the specification at pages 19-20" can comprise the probe of claim 9. While applicants' arguments are acknowledged, the art rejection is maintained. In response to applicant's first argument, the claim's recitation of "comprising a nucleotide sequence consisting of at least 20 contiguous nucleotides" is not limited by the recitation of "consisting of" but instead the more open language of comprising since the "probe comprises a nucleotide sequence consisting of", instead of the just the "probe consisting of" limitation. In response to applicant's second argument that the additional sequence found in the recited Korn et al. citation "would be inconsistent with its function as a probe", applicant is reminded that the recitation of "probe" confers no structural limitations on the sequence. The recitation of an intended use in the preamble of this product claims carries no patentable weight. It is further argued that a sequence being longer than 20 nucleotides does not preclude its use as a "probe"(ex. comparative genomic hybridization and FISH assays use entire chromosomes as "probes").

2. Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Ziegelin et al.(Accession #AJ011592, October 01, 1998).

Ziegelin et al. teach an isolated nucleic acid encoding at least 10 consecutive amino acids of SEQ ID NO:9306, wherein the nucleic acid sequence is hybridizable to a nucleic acid having a nucleotide sequence selected from SEQ ID NO:4084(See attached alignment Result 10).

Ziegelin et al. teach bases 1144-1185 of accession # AJ011592 that align with 100% identity to the nucleic acids encoding amino acids 428-441(14 amino acids) of SEQ ID NO: 9306.

Response to Arguments:

Applicant's arguments filed 5/12/2004 have been fully considered but they are not persuasive. First, applicant is to thank for pointing out the examiner's inadvertent use of 102(b) in the above rejection, applicant correctly noted that the rejection should be made under 35 U.S.C. 102(a), the correction is made herein. Second, applicant's arguments that "Ziegelin et al teaches a sequence encoding a polypeptide that is clearly not a *B. fragilis* polypeptide", that "the official action does not allege and does not show that the cited sequence would be hybridizable to a nucleic acid having a nucleotide sequence ...", and that "there is no teaching or suggestion in the reference that would direct one to modify the references sequence so as to meet the hybridization requirement" are all acknowledged but the art rejection is herein maintained. First, it should be noted that the Ziegelin et al. reference meets the only structural limitation of the claim which is that of SEQ ID NO:4084. In addition, it is argued that the nucleic acid sequence encoding(sharing 29 out of 41 nt ~ 70.7%) the amino acid sequence sharing 100% identity with SEQ ID NO:9306, would in fact be capable of hybridization under particular hybridization conditions, as the claim is void of any specific conditions, any conditions may be inferred. As a result the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 10, and New Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the language of the claim 10 and claims 30-31, indicates that they are drawn to a genus, i.e., any nucleic acid encoding a *B. fragilis* polypeptide of at least 10/20 consecutive amino acids of SEQ ID NO: 9306, wherein the nucleic acid is hybridizable/hybridizable under stringent conditions to a sequence set forth in SEQ ID NO: 4084, a complement of SEQ ID NO: 4084, or an RNA of the same wherein U is substituted for T.

The search indicates that SEQ ID NO: 4084 and SEQ ID NO: 9306 are both novel and unobvious sequences. There are only two species explicitly disclosed (a nucleic acid molecule consisting of SEQ ID NO: 4084 and the nucleic acid encoding SEQ ID NO: 9306 that are within the scope of the claimed genus).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claims

encompass any sequence capable of hybridizing, splice variants and cDNAs that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because while SEQ ID NO: 4084 is a full open reading frame or ORF(and SEQ ID NO: 9306 encodes the same), when reviewing a claim that encompasses a widely varying genus such as any nucleic acid encoding any 10 or any 20 consecutive amino acids of SEQ ID NO: 9306 that are capable of hybridizing/hybridizable under stringent conditions to a sequence set forth in SEQ ID NO:4084, a complement of SEQ ID NO: 4084, or an RNA of the same wherein U is substituted for T, the examiner must evaluate any necessary common attributes or features. In the case of a nucleic acid probe encoding a *B. fragilis* polypeptide of at least 10 or 20 consecutive amino acids of SEQ ID NO: 9306, wherein the nucleic acid is hybridizable/hybridizable under stringent conditions to a sequence set forth in SEQ ID NO:4084..." encompasses a variety of subgenera with widely varying attributes. For example, a nucleic acid probe encoding a *B. fragilis* polypeptide of at least 10 or 20 consecutive amino acids of SEQ ID NO: 9306, wherein the nucleic acid is hybridizable/hybridizable under stringent conditions to a sequence set forth in SEQ ID NO:4084, is not representative of a genus as no information has been provided regarding the location of these 10 and 20 amino acids or the properties required for hybridization. Further, the probe or isolated nucleic acid could encompass any nucleic acid sequence minimally containing SEQ ID NO: 4084. While applicants have stated that the nucleic acids can be used as molecular targets for the identification of new antimicrobial agents, probes for diagnostic assays, and targets for vaccine development, the claims are not limited to nucleic acids having these functional properties.

A description of a genus of probes or isolated nucleotide sequences may be achieved by means of a recitation of a representative number of such, defined by a nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus i.e., a sequence capable of hybridizing to SEQ ID NO:4084. Since the claimed genus encompasses genes yet to be discovered, splice variants, etc., the disclosed structural feature does not “constitute a substantial portion” of the claimed genus. Therefore, the disclosure of SEQ ID NO:4084 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO:4084, 2) partial structure of DNAs that are capable of hybridizing/hybridizable under stringent conditions to SEQ ID NO:4084, 3) the breadth of the claim as reading on genes yet to be discovered in addition to numerous splice variants and cDNAs, 4) the lack of correlation between the structure and the function of the genes and/or fusion constructs; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise a sequence capable of hybridizing under stringent conditions to SEQ ID NO:4084 and therefore the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001.

Response to Arguments:

In their response to the office action mailed on 2/12/2004, applicants respectfully traverse this rejection under written description as they assert that the “nucleic acid of claim 10 does not encompass any sequence capable of hybridizing to a recited sequence, but must also be an

isolated nucleic acid encoding a *B. fragilis* polypeptide of at least 10 consecutive amino acids of SEQ ID NO:9306". It should be noted that this point is understood and this still, large genus can be exemplified for example by the many splice variants that are encompassed by this requirement. While the office acknowledges these arguments, they maintain their position that language such as "hybridizable/hybridizable under stringent conditions" does not provide the structural requirements needed for claiming a specific sequence that is in accordance with the written description requirement. In addition, while applicant's attempt to remedy the lack of written description is noted in applicant's addition of the recitation of "hybridizable under stringent conditions", no definition of "stringent conditions" can be found in the specification on pages 20-21, only definitions of low, intermediate and high stringency conditions are briefly defined, as such no structural limitation is conferred to the novel SEQ ID NOS: of claims 10, 30 and 31.

Allowable Subject Matter

4. Claims 1-8 and 29 appear to be free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (571)272-0748. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.


If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Jeffrey Fredman, can be reached at (571)272-0742. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782. The official fax number is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (571)272-0518.

Sally Sakelaris



7/21/2004



JEFFREY FREDMAN
PRIMARY EXAMINER
7/21/04